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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/224,781	01/04/1999	BARRY M. LIBIN	1059-007	3261

7590

09/09/2005

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EXAMINER

KRASS, FREDERICK F

ART UNIT PAPER NUMBER

1614

DATE MAILED: 09/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/224,781	<b>Applicant(s)</b> LIBIN, BARRY M.	
	<b>Examiner</b> Frederick F. Krass	<b>Art Unit</b> 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 6-13-05.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 23-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 23-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### **Previous Rejections**

Unless explicitly maintained infra, all previous rejections are withdrawn.

### **Informalities**

The third line of claim 1 contains a garbled phrase beginning with the number 72, which is apparently a typographical error. It should be corrected when responding to this Office action.

### **Anticipation Rejection**

1) Claims 23-25 were rejected under 35 U.S.C. 102(b) as being anticipated by EP 0 670 711 B1.

This rejection is maintained.

Applicant contends that the nisin component of the prior art is excluded by the transitional phrase "consisting essentially of".

The examiner does not agree.

The transitional phrase "consisting essentially" of limits the scope of a claim to the specified materials or steps and "those which do not materially affect the basic and novel characteristics of the claimed invention." See MPEP 2111.03. Furthermore, if an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of", applicant has the burden of showing the introduction of additional steps or components would materially change the characteristics of applicant's invention. Id.

Applicant has not fulfilled this burden; rather, he merely arrives at a legal conclusion without supporting facts. Moreover, the facts of record do not appear to support that legal conclusion. EP 0 670 711 B1 includes nisin in combination with triclosan in order to provide a composition having a broader spectrum of activity. See p. 2, lines 15-26. This is the same general function served by Applicant's

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combination of triclosan with a cationic antimicrobial agent: see p. 3, lines 13-20 of the instant specification. Accordingly, it is not seen how nisin materially affects the basic and novel characteristics of the claimed invention.

2) Claims 23-25 were rejected under 35 U.S.C. 102(b) as being anticipated by GB 2 160 099 A.

This rejection is maintained.

Applicant contends that the urea component of the prior art is excluded by the transitional phrase "consisting essentially of".

The examiner does not agree.

Again, applicant has not fulfilled his burden of showing that the addition of urea would materially affect the basic and novel characteristics of the claimed invention. GB 2 160 099 includes urea as a softening agent, i.e. an agent which promotes absorption of the active agent into the skin. See the first paragraph of p. 2 of the prior art. This is the same general function served by Applicant's addition of a cationic antimicrobial; see and compare with the last paragraph of page 6 of the instant specification. Accordingly, it is not seen how urea materially affects the basic and novel characteristics of the claimed invention.

### **Obviousness Rejection**

Claims 23-30 were rejected under 35 U.S.C. 103(a) as being unpatentable over Libin (USP 5,236,699) in view of EP 0 670 711 B1.

This rejection is maintained.

Applicant argues that the prior art is not applicable to the claims as amended since 1) there is no teaching or direction which tells the skilled artisan to delete the nisin component of the '711 patent; 2) there is no teaching or direction which tells the skilled artisan how to use the combination of a cationic agent and triclosan to treat a fungal infection; and 3) nisin is excluded by the term "consisting essentially of".

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The examiner disagrees with this reasoning.

Arguments "1)" and "2)" represent "piecemeal" arguments which address the deficiencies of each reference individually, rather than addressing what is fairly suggested by their combined teachings. The examiner stands by the reasoning provided in the previous Office action.

Regarding argument "3)", the examiner does not agree that nisin is excluded by the term "consisting essentially of", for the reasons outlined in subsection "1)" of the "Anticipation" rejection supra.

#### **Action is Final**

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

#### **Correspondence**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frederick F. Krass whose telephone number is 571-272-0580. The examiner's schedule is 9:30AM – 6:00PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached at 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frederick Krass  
Primary Examiner  
Art Unit 1614

